Remarks

Prior to this Amendment, claims 1-81 were pending. By this Amendment, claims 1-38 and 60-81 have been canceled, solely in response to the Restriction Requirement. The Applicants reserve the right to pursue these claims in continuing applications.

The specification has been amended to include the priority claim.

Claim objections

Claims 39-59 were objected to because of the typographical error of "or" rather than "of" in the last line.

Clam 39 has been amended to correct this typographical error. Accordingly, it is respectfully requested that this objection be withdrawn.

Claim 48 was objected to because the terms "CpG" and "GM-CSF" were viewed as abbreviations.

Claim 48 has been amended to spell out that "GM-CSF" refers to granulocyte-macrophage colony-stimulating factor. The term "CpG" has not been amended because CpG is not an abbreviation. Instead, it refers to a particular immunostimulatory dinucleotide motif found in DNA. See the specification, at page 10, lines 15-19: "... adjuvant compositions which comprise bacteria derived substances such as monophospholipid A or cell wall skeleton (CWS), DNA having immunostimulatory CpG motifs and immunostimulatory cytokines such as

granulocyte-macrophage colony-stimulating factor (GM-CSF) and interleukin 2 (IL-2)." Accordingly, it is respectfully requested that this objection be withdrawn.

The rejections under 35 U.S.C. §112, second paragraph

Claim 44 was rejected as being indefinite because of the use of the word "derivative."

The Applicants do not agree with this rejection. However, in the interests of expediting prosecution, and without prejudice to the further prosecution of claim 44 in continuing applications, claim 44 has been amended to delete the phrases in which the word "derivative" appears.

Claim 48 was rejected as being indefinite because of the use of the phrase "semi-synthetic saponin-like molecule."

The Applicants do not agree with this rejection. However, in the interests of expediting prosecution, and without prejudice to the further prosecution of claim 48 in continuing applications, claim 48 has been amended to delete the phrase "semi-synthetic saponin-like molecule."

The rejection under 35 U.S.C. §112, first paragraph

Claims 39-59 were rejected for lack of enablement. The Office Action cited numerous publications that allegedly show that the state of the art is such that "no one skilled in the art would accept the assertion that the method comprising administering alpha-(2-8)-polysialic acid-carrier conjugate and an adjuvant would be effective in

treating small cell lung cancer or neuroblastoma." See the Office Action, page 8, lines 19-22.

The Applicants respectfully submit that the evidence cited in the Office Action is insufficient to support this rejection because the evidence is not relevant to the invention being claimed. Although directed to the general area of cancer treatments, the publications cited are not directed to the particular types of treatment being claimed.

For example, Gura (Science, 1997, 278:1041-1042) is not concerned with stimulating an immune response which leads to the production of antibodies that attack tumor cells, but instead is concerned with screening for drugs that act directly on tumor cells. Screening is not relevant to the present invention because the present claims recite the "drug" that is to be used: an α-(2-8)-polysialic acid-carrier conjugate. There is no need for screening to practice the claimed invention.

Jain (Sci. Am., 1994, 271:58-65), like Gura, does not discuss the use of compositions to stimulate an immune response against tumor cells.

Curti (Crit. Rev. in Oncology/Hematology, 1993, 14:29-39) is generally concerned with chemotherapeutic drugs, which, since they are directly toxic to tumor cells, act in a very different manner from the α-(2-8)-polysialic acid-carrier conjugate recited in the present claims.

Hartwell et al. (Science, 1997, 276:1064-1068) is directed to discovering new targets and new drugs for targets, i.e., screening. As explained above, the present claims do not require such screening.

Ezzel (J. NIH Res., 1995, 7:46-49) was cited for the supposed fact that "tumor immunologists are reluctant to place bets on which cancer vaccine approach will prove effective in the long run" and for some supposed doubts about the efficacy of

single peptides. The Applicants submit that the betting habits of tumor immunologists on vaccines in general says nothing about the enablement of the particular methods being claimed and that the present claims do not require the use of peptide antigens but require instead an α-(2-8)-polysialic acid-carrier conjugate.

Spitler (Cancer Biotherapy, 1995, 10:1-3) was cited because of the statement: "Ask practicing oncologists what they think about cancer vaccines and you're likely to get the following response: 'cancer vaccines don't work.' Ask a venture capitalist or the director of product development at a large pharmaceutical company and you're likely to get the same response." Spitler suffers from the same defect as Ezzell. Spitler does not deal with the particular methods being claimed. General doubts do not show lack of enablement for particular claims. Furthermore, the Office Action did not demonstrate that venture capitalists and directors of product development are among those of ordinary skill in the art. Thus, their opinions, even if accurately portrayed in Spitler, are not relevant here.

Boon (Adv. Can. Res., 1992, 58:177-210) focuses on the problem of immune tolerance, i.e., the inability to mount an immune response against tumor antigens. The prospect of immune tolerance does not lead to a lack of enablement for the present claims because the specification provides evidence that the claimed methods lead to the production of antibodies that can recognize and even lyse tumor cells having the relevant polysialic acid antigens. That is, the evidence in the specification shows that immune tolerance can be overcome by the present invention. See Examples 2 and 3.

At page 9, line 1 to page 11, line 4, the Office Action cites further publications. The cited publications are concerned with tumors other than small cell lung cancer and neuroblastoma. Nevertheless, the Office Action states that these publications support the proposition that "one cannot predict whether primary small

cell lung cancer cells or primary neuroblastoma or metastatic cells thereof would express an adequate amount of polysialic acids on the cancer cell surface to be an effective target for the antibodies to kill cancer cells." The specification proves that this proposition is false by providing evidence which demonstrates the existence of polysialic acids that can be recognized by antibodies on the surfaces of small cell lung cancer and neuroblastoma cells. See, e.g., page 2, lines 8-11: "A study using monoclonal antibodies (mAbs) against polysialic acid demonstrated that this molecule is distributed on SCLC and neuroblastoma cells (Zhang, 1997). For example, polysialic acid was detected on 6 of 6 SCLCs and 5 of 5 neuroblastomas but not on any of the other cancer cells tested." See also page 2, lines 26-28: "The embryonal form of N-CAM, modified with long sialic acid polymers, is found on the great majority of neuroblastomas and SCLC cells (Troy, 1992; Zhang et al., 1997)."

Page 9, line 1 to page 11, line 4 of the Office Action further claims that a variety of differences may arise between cultured tumor cell lines and the tumors from which the cells were derived. Even if this is true, however, the specification provides evidence that this will not present problems for the enablement of the present invention. The specification provides actual data, in part from human clinical trials. The data demonstrate that the antibodies raised by practicing the claimed methods can recognize and even lyse tumor cells having the relevant polysialic acid antigens. See Examples 2 and 3. Thus, whatever problems the cited publications discuss that might sometimes arise are capable of being overcome.

In view of the above, it is respectfully requested that this rejection be withdrawn.

Claim 44 was rejected for lack of enablement because of the recitation of bovine serum albumin.

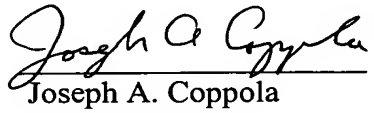
The Applicants do not agree with this rejection. However, in the interests of expediting prosecution, and without prejudice to the further prosecution of claim 44 in continuing applications, claim 44 has been amended to delete recitation of bovine serum albumin. Accordingly, it is respectfully requested that this rejection be withdrawn.

The time for responding to the Office Action was set for February 2, 2006. Enclosed herewith is a Petition for the Extension of Time under 37 C.F.R. § 1.136(a) for a period sufficient to permit the filing of this response.

The Applicants hereby also make a Conditional Petition for any relief available to correct any defect seen in connection with this filing, or any defect seen to be remaining in this application after this filing. The Commissioner is authorized to charge Kenyon & Kenyon's Deposit Account No. 11-0600 for any fees associated with such Conditional Petition.

Respectfully submitted,

Date: May 2, 2006

By: 

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